K100591

1 of 2

510(k) Summary

JAN 24 2011

510(k) owner: Abigo Medical AB
Ekonomivagen 5
Askim, Sweden
+46 31 748 4971

Contact Information: C. G. Bundy Associates, Inc.
435 Rice Creek Terrace NE
Fridley, MN 55432 USA
Phone: 763-574-1976
Fax: 763-571-2437

Date of summary: February 26, 2010, Revised November 30, 2010

Device Name: Proprietary Name: Sorbact® gel
Common/Classification Name: Wound Dressing

Classification Regulation: Unclassified, Class II medical device

Product Code: FRO

Predicate Device Identification: Sorbact® Wound Dressing, K063059

Device Description: Sorbact gel Wound Dressings are sterile bandages that attract and capture water-repelling (hydrophobic) microorganisms.

Intended Use: OTC: Sorbact Gel Wound Dressing is intended for use in the management of minor wounds (dry to low exuding) and to attract water repelling germs. The dressing may be used on minor scrapes, cuts, sores and burns.

Rx: Sorbact Gel Wound Dressing is intended for use in the management of dry to low exuding partial to full thickness wounds (including clean, colonized, contaminated or infected wounds).The dressing is indicated for post-operative wounds, trauma wounds, shallow cavity wounds, fistulas, pressure ulcers, diabetic ulcers, and venous ulcers.

DLC 1/24/11

Technological characteristics, comparison to predicate device:

Sorbact® Wound Dressings are sterile bandages that attract water-repelling (hydrophobic) microorganisms. The dressings are coated with DACC (dialkyl carbamoyl chloride), a hydrophobic (water-repelling) fatty ester acid that atracts and reduces the overall concentration of hydrophobic microbes in a wound each time the dressing is changed. The original Sorbact Wound Dressing has been modified by the addition of a hydrogel. The hydrogel addition allows effective management of low exuding dry wounds and creates a moist wound healing environment.

The Sorbact® gel was compared against the original Sorbact wound dressing regarding the ability to bind hydrophobic microbes and water repelling germs. Results of the test were identical for both devices.
Sorbact gel was tested for biocompatibility and the following tests were conducted:

- Skin Sensitization
- Cytotoxicity
- Skin Irritation

Sorbact gel passed all tests.

Conclusion: The Sorbact gel has identical features, performance and intended use as the original Sorbact wound dressing. Results of comparative performance testing against the predicate device show that Sorbact® gel is substantially equivalent to devices on the market (cleared by the 510(k) process).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

JAN 24 2011

Abigo Medical, AB
% C.G. Bundy Associates, Inc.
Ms. Constance G. Bundy
435 Rice Creek Terrace
Fridley, Minnesota 55432

Re: K100591
Regulatory Class: Unclassified
Product Code: FRO
Dated: January 11, 2011
Received: January 19, 2011

Dear Ms. Bundy:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

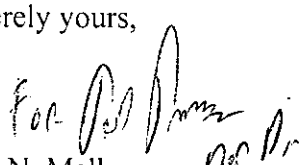
CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K100591

Device Name: Sorbact® Gel Wound Dressing

Indications for Use:

OTC: Sorbact Gel Wound Dressing is intended for use in the management of minor wounds (dry to low exuding). The dressing may be used on minor scrapes, cuts, sores and burns.

Rx: Sorbact Gel Wound Dressing is intended for use in the management of dry to low exuding partial to full thickness wounds (including clean, colonized, contaminated or infected wounds). The dressing is indicated for post-operative wounds, trauma wounds, shallow cavity wounds, fistulas, pressure ulcers, diabetic ulcers, and venous ulcers.

Prescription Use __X_____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ___X____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David Krause for MXM

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K100591